

4/P2/b

WO 2004/012644

PCT/GB2003/003348

1

# AN INFLATABLE DEVICE FOR USE IN IMPULSE THERAPY

## FIELD OF THE INVENTION

The present invention relates to a device for use in intermittent impulse therapy,  
5 particularly but not exclusively for applying intermittent impulse pressure to a human foot to enhance blood circulation around the body.

## BACKGROUND OF THE INVENTION

The use of an inflatable garment applied to a limb or other area of the human body  
10 as a means of enhancing blood circulation is a well established medical technique with proven clinical benefits.

Such a device, known as the A-V Impulse System® is in widespread use and is  
designed to apply intermittent impulses to the foot in such a manner as to mimic  
15 ambulatory movement which is known periodically to empty the veins of the foot to drive the blood throughout the body.

The A-V Impulse System® comprises an inflatable bladder being part of or integral  
with means in the form of a foot wrap for securing the bladder in the plantar arch of  
20 the foot and about the area to be treated.

During use the bladder is filled with a fluid such as air to expand and apply cyclical  
force to the plantar arch directed in such a way as to empty the plantar veins of the  
foot.

25

Best Available Copy

The bladder is held pressurised for a period before releasing the fluid and then the cycle is repeated.

The rate of filling or venting of the bladder may vary from fractions of a second to several seconds according to application, but is dependent upon the bladder volume, fluid flow rate and operating pressure.

To be effective the bladder has to be filled rapidly and the consequent high velocity flow of fluid results in the generation of noise as the fluid passes from the controlling system through the connecting tubing into the bladder.

Noise reduction may be achieved by reducing the fluid flow rate but this is not a feasible remedy because it affects the required rate of pressurisation and desired operating characteristics.

#### SUMMARY OF THE INVENTION

It is an object of the present invention to overcome the disadvantages of the prior art by providing the inflatable bladder with an internal volume reducing media or component providing means whereby the same bladder pressurisation is achievable with a lower rate of fluid flow compared with the prior art. A lower rate of fluid flow means lower fluid usage and a reduction in the generation of noise which occurs

when the bladder is being filled. Thus patient comfort is increased while maintaining the effectiveness of the therapy treatment.

According to the present invention there is provided a device for use in applying  
5 impulse therapy to a limb of the human body comprising an inflatable bladder,  
means for providing intermittent pulses of fluid to the bladder in accordance with a  
pre-determined timed sequence of pressure hold and pressure release, means for  
securing the bladder around the limb of the human body to apply the bladder to the  
area to be treated, characterised in that the bladder is provided with a volume  
10 reducing internal component which acts to dissipate the flow of fluid into the  
bladder with accompanying reduction in fluid flow rates and noise generated by the  
fluid flow during pressurisation of the bladder.

Preferably the internal media is of foam material which may be attached to internal  
15 walls of the bladder or fitted loosely within the bladder without attachment.

It may be advantageous to provide the foam with channels for movement of  
pressurised air within the bladder.

20 Other features and advantages will now be described with reference to a set of  
accompanying drawings.

**BRIEF DESCRIPTION OF THE DRAWINGS**

The invention will now be described by way of example with reference to the accompanying drawings wherein:

5    Figures 1 and 2 show, in plan and cross-sectional view respectively, a device for applying impulse therapy to a human foot;

Figures 3 and 4 show respectively a side and front view of the device of Figures 1 and 2 as applied to a human foot;

10

Figures 5 and 6 show in plan and cross-sectional view respectively, a device for impulse therapy of the human foot in accordance with the invention;

Figures 7 and 8 show the a side and front view respectively of the device of Figures 15    5 and 6 applied to a human foot;

Figure 9 shows the device of Figure 5 and 6 with part of the outer covering cut away to show the internal media of the bladder of the device;

20    Figure 10 shows a plan view of the device of Figures 5 and 6 with part of the outer covering of the device cut away to reveal the internal media of the bladder partly-filled by an amount sufficient to occupy the plantar arch of the human foot;

Figure 11 is a cross-sectional view of the device of Figure 9;

25

Best Available Copy

Figure 12 is a cross-sectional view through the internal media within the bladder of the device of Figure 10 illustrating a preferential profile of the internal media designed to occupy the plantar arch of the foot; and

5 Figure 13 shows a plan view of the device in accordance with the invention with part of the outer covering of the device cut away to reveal the internal media of the bladder provided with air flow channels cut into the media.

#### 10 BEST MODES OF CARRYING OUT THE INVENTION

A device for intermittent impulse therapy to be applied to the human foot is shown in Figures 1, 2, 3 and 4 in accordance with the prior art.

The device comprises an inflatable bladder or pad formed from two films 1, 2 of  
15 flexible polymeric material joined at the periphery 3 by, for example, radio frequency (RF) welding to form an essentially sealed pressure vessel or bladder 4.

The bladder 4 is formed integral with a foot wrap 5, see Figure 3, which can be secured, as by velcro action, around the foot 6 as shown in Figures 3 and 4 to hold  
20 the bladder 4 generally within the plantar arch 7 of the foot 6 with a void 4 between the bladder 4 and foot arch.

A port connection 8 is sealed to one of the films 1, 2 of the bladder 4 with a connection tube 9 attached to the port 8 to allow air to be admitted and vented  
25 from the bladder 4.

As pressurised air is fed to the bladder 4, the bladder 4 is free to expand particularly into the arch 7 of the foot 6 and elsewhere over the bladder surface area, being constrained only by the foot itself and by resistance to outward expansion of the wrap 5 to which the bladder is attached.

During inflation of the bladder 4 air flows through the port connection 8 at high velocity which generates excessive noise caused by the geometry within the flow path of the air and by pressurised air impinging directly on to the inner wall 5 of the bladder 4 opposite the port connections 8.

It is to the elimination of the excessive noise caused by the movement of pressurised air as described that the present invention is directed and in this way to improve the performance of the impulse therapy device and enhance patient fit up, comfort and well-being.

The improved impulse therapy device in accordance with the invention is illustrated in Figures 5 through 13.

In these embodiments the device itself is constructed in accordance with the prior art as discussed with reference to Figures 1 through 4 with the exception that in accordance with the invention the bladder 4 is provided with an internal media 10 in the form preferably of a foam, gel or fluid reservoir which reduces the internal volume of the bladder. The internal media in accordance with the invention may be

attached to one or other, or both, films of the bladder 4. Alternatively, it may be freely inserted within the bladder 4.

5 The internal media acts to dissipate the flow of fluid within the bladder thus reducing noise and also the amount of fluid necessary to achieve the required rate of pressurisation.

10 The improved bladder 4 of the impulse therapy device in accordance with the invention may be constructed by forming the internal media 10 by an injection moulding process, either applied to bladders formed in accordance with the prior art or as part of multi-shot process to manufacture a bladder with an internal media by automated means, using for example a thermoplastic elastomer polymer together with a foaming technique to produce an integral cellular construction as the internal media.

15

The improved impulse therapy device in accordance with Figures 5 and 6 is shown applied to a human foot in Figures 7 and 8 in like manner as with the conventional impulse therapy device illustrated in Figures 3 and 4.

20 Whereas in the Figure 5 embodiment the media 10 fills the entire space within the bladder 4 in alternative form the media may be appropriately profiled 10' within the bladder such that when the device is applied to the foot the media conforms to the plantar arch 7, as illustrated with reference to Figures 10, 11 and 12.

The internal media 10 may be constructed from either a closed cell or open cell form according to the desired benefits of internal bladder volume reduction consistent with suitable air flow either immediately through and within the media, with channels 11 formed or cut into the media as shown in Figure 13 or over and  
5 around the media.

The inclusion of an internal media within the bladder of the impulse therapy device as described above and in accordance with the invention, has significant actual and perceived implications for user comfort leading to improved product acceptance,  
10 compliance and clinical results.

In addition, a specific improvement has been observed when using the improved impulse therapy device in accordance with the invention fitted more loosely than is recommended with the prior art device as described with reference to Figures 1  
15 through 4. Without inclusion of the internal media within the bladder it is necessary to fit the garment to the foot relatively snugly to avoid over-inflation and thus excessive air consumption. A disadvantage of such a fit-up is to cause a static force to be applied to the limb throughout the uninflated phase of applied impulse pressure thereby to some extent hindering re-priming of the veins of the foot  
20 following evacuation.

With the inclusion of the internal media the necessity to tighten the device as snugly as previously is reduced and consequently the static force on the foot is lessened allowing superior re-priming of the veins of the foot to occur.  
25